

REMARKS

Claims 17-35 were pending in the present application upon mailing of the Office Action. Claim 17 has been amended. Claims 24-33 and 35 have been canceled without prejudice. Claims 36-42 have been added. No new matter has been added by these amendments. Upon entry of this amendment, claims 17-23, 34 and 36-42 will be pending.

Applicant has amended the title of the application to maintain consistency between the title and the claimed subject matter. Support for this amendment may be found in the original title on page 1 of U.S. Patent Application Publication No. US 2004/0156910.

Support for the amendment to claim 17 may be found, *inter alia*, on page 3, paragraph [0033] of U.S. Patent Application Publication No. US 2004/0156910.

Support for new claim 36 may be found, *inter alia*, on page 3, paragraph [0033] of U.S. Patent Application Publication No. US 2004/0156910.

Support for new claim 37 may be found, *inter alia*, on page 3, paragraph [0033] of U.S. Patent Application Publication No. US 2004/0156910.

Support for new claim 38 may be found, *inter alia*, on page 3, paragraph [0033] of U.S. Patent Application Publication No. US 2004/0156910.

Support for new claim 39 may be found, *inter alia*, on page 3, paragraph [0033] of U.S. Patent Application Publication No. US 2004/0156910.

Support for new claim 40 may be found, *inter alia*, on page 4, paragraph [0036] of U.S. Patent Application Publication No. US 2004/0156910.

Support for new claim 41 may be found, *inter alia*, on page 3, paragraph [0033] of U.S. Patent Application Publication No. US 2004/0156910.

Support for new claim 42 may be found, *inter alia*, on page 4, paragraph [0037] of U.S. Patent Application Publication No. US 2004/0156910.

Applicant respectfully requests that the amendments and remarks made herein be entered and fully considered.

Information Disclosure Statement

Applicant submits a Supplemental Information Disclosure Statement, a List of References Cited and copies of references C25-C49.

Claim Rejections - 35 U.S.C. § 112

Claims 17-35 were rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for administering to a subject an amount of a dietary indole, allegedly does not provide enablement for a method of preventing endometriosis and/or one or more symptoms associated with endometriosis. Without admitting to the propriety of the rejection and in an effort to advance prosecution of the present application, Applicant has amended claim 17 to delete “or preventing” and “or in danger of developing endometriosis” so that it now recites “a method of treating endometriosis in a subject having endometriosis.” Thus, the rejection has been obviated. Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Furthermore, Applicant has added new claims 36-42. In accordance with the Examiner’s suggestion, new claim 36 recites “A method of reducing the risk of endometriosis in a subject in danger of developing endometriosis” Applicant submits that these claims conform to the Examiner’s suggestion and are allowable.

Claim Rejections – 35 U.S.C. § 103

Claims 17-33 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Liang Jin *et al.*, 1999, Cancer Research 59:3991-3997 (hereinafter “Liang”) in view of U.S. Patent No. 6,001,868 (hereinafter “Firestone”), and U.S. Patent No. 5,981,568 (hereinafter “Kunz”) and further in view of Symonds *et al.*, “AGUS in cervical endometriosis,” J. Reprod. Med. 1997 Jan; 42(1):39-43 (hereinafter “Symonds”). Applicant respectfully traverses.

In response, Applicant directs the Examiner attention to the Declaration of Michael A. Zeligs Under 37 C.F.R. § 1.131, dated September 20, 2007 (hereafter “the Zeligs Declaration”), which shows that he made the claimed invention before publication of Liang. Dr. Zeligs is the inventor on the captioned application. In paragraphs 5-7, Dr. Zeligs describes that by April 26, 1999, *i.e.*, prior to the August 15, 1999 publication date of Liang, he had conceived of and actually reduced to practice a method of treating endometriosis by the administration of a dietary indole, *e.g.*, diindolylmethane (“DIM”).

In paragraph 5, Dr. Zeligs refers to his issued U.S. Patent No. 6,689,387 B1 (“the ’387 patent”), which issued from an application filed September 23, 1999. The captioned application is a continuation of that application. Dr. Zeligs stated in paragraph 5 of his declaration that the acts described in Section 12 of the ’387 patent (column 14, line 30 to

column 15, line 15) were carried out by him or at his direction in the United States of America prior to April 26, 1999.

Prior to August 15, 1999, Dr. Zeligs had treated several patients with known endometriosis with DIM, observing beneficial clinical responses. In paragraph 6 of his Declaration, Dr. Zeligs describes the successful treatment of a 32 year old woman (“P.M.”) with endometriosis by the administration of DIM. Prior to administration of DIM, P.M.’s symptoms of recurrent midcycle and menstrually associated pain had been diagnosed as due to endometriosis based on pelvic laparoscopy. This procedure confirmed aggressive endometriosis with ectopic endometrial implants removed from the pelvis and associated with intestinal serosal spread. A history of 2 years of intense pelvic pain at mid-cycle and during menstrual flow was reported prior to the laparoscopy. Following the patient’s laparoscopy, one menstrual period was still associated with significant, continuing pain. The persisting pain and elevation of serum Ca-125 antigen level (54.1 units/ml) before DIM therapy confirmed ongoing, active endometriosis.

Treatment with “processed DIM” was begun approximately 6 weeks following the laparoscopy. The initial dose of 300 mg/day of processed DIM was reduced to 150 mg/day of processed DIM after one month. Since starting treatment, there was disappearance of pain at midcycle and improvement of pain associated with menses. The prolonged reduction of the elevated Ca-125 antigen level during DIM use (26.4, 23.2, and 34.0 units/ml) provided additional, objective evidence supporting the therapeutic response to DIM. The patient continued treatment with processed DIM for about one year. During this time, regular menstrual periods became more comfortable, no longer requiring analgesics. Therefore, the treatment of a patient with endometriosis with processed DIM achieved positive results. See paragraph 6 of the Zeligs Declaration.

In paragraph 7, Dr. Zeligs discusses P.M.’s chart note from April 26, 1999, documenting the success of this treatment and that she had been treated with “IndolplexTM,” BioResponse’s trademark for its “processed DIM.”

Therefore, well before the publication date of Liang, *i.e.*, before August 15, 1999, Dr. Zeligs had treated a patient having endometriosis with a dietary indole, DIM, and showed that the patient’s endometriosis symptoms and Ca-125 antigen level had been significantly reduced by April 26, 1999. Thus, Dr. Zeligs had conceived of and actually

reduced to practice a method of treating endometriosis by the administration of a dietary indole, *e.g.*, DIM, prior to the August 15, 1999 publication date of Liang.

Therefore, Liang is not available to the Examiner as prior art to the claimed invention. Furthermore, the Examiner has not provided any other reference that discloses a method of treating endometriosis comprising administering a dietary indole. Accordingly, Applicant respectfully submits that there is no *prima facie* case of obviousness and requests that the rejection under 35 U.S.C. § 103(a) over Liang in view of Firestone and Kunz, and further in view of Symond, be withdrawn.

Claims 34 and 35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Liang in view of Firestone, Kunz, and Symonds and further in view of U.S. Patent No. 5,993,887 (hereafter "Harris"). Applicant respectfully traverses.

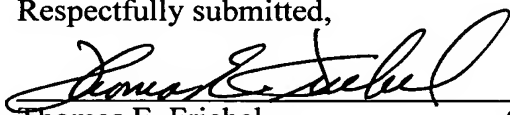
Applicant has canceled claim 35. Furthermore, as noted above, Liang is not available as a prior art reference in view of the Zeligs Declaration. Therefore, the resulting references of the rejection do not teach all the limitations of the rejected claims. For the above reasons, Applicant respectfully submits that there is no *prima facie* case of obviousness. Applicant respectfully requests that the rejection of claim 34 under 35 U.S.C. § 103(a) as allegedly being obvious over Liang in view of Firestone, Kunz, and Symond, and further in view of Harris, be withdrawn.

CONCLUSION

Applicant respectfully requests that the above-made amendments and remarks be entered and made of record in the file history of the captioned application.

Respectfully submitted,

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